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09/245,549	02/05/99	ZERVOS	A 102877039001

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EXAMINER

TUNG, J

ART UNIT  
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/245,549

Applicant(s)

Zervos

Examiner

Joyce Tung

Art Unit

1656



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 6/14/2001.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-27 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-27 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). 14

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

In light of the following new ground of rejection, the finality of the Office action mailed 1/30/2001 is withdrawn.

### ***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-6 and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2-6 and 26, the phrase "preferably first" includes the elements which is not recited in the claims. This is the same as the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 U.S.C. § 103***

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12, 15-22, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minshull et al. (5,837,458).

As to the limitations of claims 1-12, 15-22, 25 and 27, Minshull et al. disclose a method of evolving a biocatalytic activity of cell. The method applies homologous recombination technique to produce a library of recombinant genes in which the segment differs from each other in at least two nucleotides (See column 2, lines 40-45.) The method involves in Vivo formats plasmid-plasmid recombination. The initial substrates for recombination are a collection of polynucleotides comprising variant forms of a gene and the variant forms show substantial sequence identity to each other sufficient to allow homologous recombination between substrates

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(See column 7, lines 53 to column 8, lines 1-20). Plasmid containing diverse substrates are initially introduced into cells by any method (As recited in claims 1-12, 15-22, 25 and 27). In general, any type of cells can be used as a recipient of evolved gene, for example bacterial cells and yeast (See column 13, lines 31-46) (as recited in claims 7-8).

Minshull et al. also disclose in vitro formats involving at least one cycle of amplification which can be conducted using a collection of overlapping single stranded DNA fragments of related sequence and different length (See column 6, lines 35-41) (As recited in claims 2-6).

Minshull et al. do not disclose constructing a kit to perform the method.

One of ordinary skill in the art would have been motivated to apply the method of Minshull et al., because the method of Minshull et al. involves homologous recombination technic to produce a DNA library as disclosed and in which the recursive sequence recombination technique can be used for the host determination genes to be modified to grow on the new host in greater growth rates (See column 34, lines 58 and column 35, lines 1-8).

Constructing a kit including all components needed to perform a method was well known in the art at time of the instant invention. It would have been prima facie obvious to carry out the method as claimed.

5. Claims 13 -14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minshull et al. (5,837,458) as applied to claims 1-12, 15-22, 25 and 27 above, and further in view of Fraser et al. (4,870,023).

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The teachings of Minshull et al. are set forth in section 4 above and Minshull et al. do not disclose using a adapter to ligate the nucleic acid insert molecule in which the adapter has a sequence homologous to the first and second region of the vector respectively as recited in claims 13 and 14.

As to the limitations of claims 13-14 which further limits to claim 1, Fraser et al. disclose the invention directed to recombination of baculoviruses which encode fusion polyhedrin protein (See the Abstract). The gene can be expressed via homologous recombination in vivo with a parent vector (See column 9, lines 25-30). The method involves using a linker which ligates the polyhedrin DNA into a cloning vector (See column 17, lines 9-14). The linker of Fraser et al. has the same function as the adapter claimed in instant claims 13-14.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of the references of Minshull et al. and Fraser et al. with a reasonable expectation of success because the method of Minshull et al. involves homologous recombination technique to produce a DNA library as disclosed and in which the recursive sequence recombination technique can be used for the host determination genes to be modified to grow on the new host in greater growth rates (See column 34, lines 58 and column 35, lines 1-8). and the method of Fraser et al. is useful for express vector (See column 3, lines 2-5). It would have been prima facie obvious to make the adapter as claimed.

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6. Claims 23-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minshull et al. (5,837,458) as applied to claims 1-12, 15-22, 25 and 27 above, and further in view of Liu et al. (5,928,868).

The teachings of Minshull et al. are set forth in section 4 above and Minshull et al. do not disclose that the DNA library is screened in a two hybrid system.

Liu et al. disclose a method and kit for characterizing small molecules from a small molecule library (See the Abstract). The cells respectively contains a first and second expression vector including a DNA encoding a known first and second target linked to a first and second transcriptional module selected from a DNA binding protein and a transcriptional activator (See column 14, lines 9-67). The cells contains a reporter gene. The expression of the reporter gene is conditioned on the proximity of the first and second hybrid proteins to each other, if the hybrid ligand binds to target sites on both hybrid protein. The cells express the reporter gene which are selected (See the Abstract). The method is rapid to identify a small molecule (See column 2, lines 25-30).

One of ordinary skill in the art would have been motivated to combine the teachings of the references of Minshull et al. and Liu et al. with a reasonable expectation of success because the method of Minshull et al. involves homologous recombination technique to produce a DNA library as disclosed and in which the recursive sequence recombination technique can be used for the host determination genes to be modified to grow on the new host in greater growth rates (See column 34, lines 58 and column 35, lines 1-8) and the method of Liu et al. is rapid to

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screen a small molecule (See column 2, lines 25-30). It would have been prima facie obvious to carry out the method as claimed.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

October 11, 2001

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600